

## REMARKS

Remarks appear in the order presented in Paper 13.

### Formal Matters

Applicants note in the Formal Matters that each of the Groups restricted in Paper 6 are to be combined and searched. Applicants appreciate the Examiner's consideration of this matter. The Office Action Summary refers to claims 20-28 as being withdrawn, which is assumed to be an oversight, as claims 20-28 have been examined. If Applicant's assumption is in error, please advise.

### Claim rejections under 35 U.S.C. § 112, ¶1 for enablement and written description

Claims 1-28 are rejected under 35 U.S.C. § 112, ¶ 1 "because the specification, while being enabling for pharmaceutical compositions using fragments of MSH ending in KPV, including SEQ. ID. NOs: 3, 4 and 8 and methods of treating candidiasis, does not reasonably provide enablement for pharmaceutical compositions comprising any and all proteins which have a C-terminal sequence KPV or for methods of treating all oral pathologies." (Office Action, Paper 13, pg. 2.) The Office Action also rejects claims 1-28 based on a lack of sufficient written description. Applicants' traverse the above rejections, however, to expedite allowance of the claims, the claims have been amended to recite the peptides of SEQ. ID. NOs: 1, 3, and 8.

### Claim rejections under 35 U.S.C. § 103(a)

Claims 1-28 are rejected under 35 U.S.C. § 103(a) as obvious in view of Catania *et al.* (Catania) in view of Applicants' specification. Claims 1-28 are separately rejected

as obvious over Mahe, *et al.* (Mahe) in view of Applicants' specification. Claims 1-28 are separately rejected as obvious in view of Csato *et al.* (Csato) in view of Applicants' specification. Claims 1-28 are rejected as obvious over Lipton *et al.* (Lipton). Applicants respectfully traverses each rejection.

i. Catania in view of Applicants' specification.

In order for Catania to be cited as a reference under 103(a) it must qualify as a reference under 35 U.S.C. § 102.

Catania is an application filed in the United States and bears a publication date of 2002 which postdates the filing date of the instant application (1/29/01). Thus, it is not a 102(b) reference. Since there existed an obligation to assign the invention to the same person ("Zengen") at the time the invention was made under 35 U.S.C. § 103(c), Catania cannot be a 102(e), (f) or (g) reference. Please remove Catania as a § 103(a) reference.

ii. Mahe.

The Office Action states that "Mahe *et al.* teach the use of "KPV" compounds in the treatment of inflammation (Abstract) as well as methods of using these compounds to treat inflammation (inherent from the entire document)." Although the Office Action acknowledges that Mahe does not teach the use of KPV as a fungicide, the Office Action concluded it would have been obvious to combine fungicide or antibiotics with KPV. Mahe teaches only KPV as opposed to other fragments of  $\alpha$ -MSH. Further, Mahe does not identify any antibacterial activity of KPV. It would not be obvious to one

of ordinary skill in the art at the time the invention was made to modify Mahe to include a fungicide or antibacterial.

One skilled in the art would not modify Mahe to add a fungicide, as nothing in Mahe suggests a use to treat infection. Nor does Mahe posit that the inflammation it seeks to treat was secondary to an infection. Further, Mahe teaches a topical use for the compounds recited in Mahe but does not suggest an oral use. The claims of the instant application are directed to oral infections. Applicants respectfully requests that Mahe be removed as a § 103(a) reference.

iii. Csato in view of Applicants' specification.

The Office Action states that: "Csato, et al. teach the use of KPV compounds in the treatment of the fungal pathology produced by *Candida albicans*." However, Csato does not teach either the use of KPV compounds or KPV compounds in the treatment of fungal pathology.

First, the claims as amended do not recite  $\alpha$ -MSH (SEQ. ID. NO. 4). On this basis alone, Csato should be removed as a § 103(a) reference as no mention, suggestion, or motivation exists in Csato to modify the reference to specific fragments of  $\alpha$ -MSH for the treatment of oral candidiasis.

Second, Csato does not suggest the treatment of candidiasis through the application of  $\alpha$ -MSH. Nor does Csato teach that application of  $\alpha$ -MSH reduces the viability of *Candida* cells but instead teaches that the *Candida albicans* killing activity of separated human epidermal cells may be enhanced with the addition of  $\alpha$ -MSH. Csato at p. 145. Thus, Csato suggests that it is not  $\alpha$ -MSH that reduces the viability of

*Candida* cells but a combination of separated human epidermal cells, imbued with their own anti-*Candidal* killing ability, and  $\alpha$ -MSH. Csato teaches only that  $\alpha$ -MSH enhanced the killing of *Candida* by epidermal cells. This is verified in Csato where the author compares the enhancement observed with  $\alpha$ -MSH to the enhancement observed when epidermal cells are induced by ultraviolet light. (Csato at p. 145.) Csato suggests this enhancement may be due to  $\alpha$ -MSH's effect on Merkel cells but nowhere teaches that  $\alpha$ -MSH be used as an anti-microbial. Thus, Csato lacks any teaching of a fungicidal activity of  $\alpha$ -MSH or fragments thereof. It is respectfully requested that Csato be removed as a § 103(a) reference.

iv. Lipton.

Paper 13 states: "Lipton, et al. teach the use of KPV compounds in the treatment of inflammation as well as methods of using these compounds to treat inflammation." (Paper 13, p. 6.) Until later studies by Lipton, the antimicrobial activity of fragments of  $\alpha$ -MSH had not been accepted. It would not have been obvious or even desired at the time to enhance antimicrobial activity by modifying Lipton as the antimicrobial properties of  $\alpha$ -MSH fragments had yet to be discovered. It would not have been obvious to use fungicide with KPV at the time the instant invention was made given these teachings.

In view of the foregoing, it is submitted that this application is in condition for allowance, and a Notice of Allowance is requested.

Respectfully submitted,

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